Novus Therapeutics Doses First Subjects in Phase 1 Study of OP0201

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IRVINE, Calif.--(BUSINESS WIRE)--Nov. 27, 2018-- Novus Therapeutics, Inc. (NASDAQ: NVUS), a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat (ENT), today announced that it has dosed the first adult subjects in the low dose cohort of a phase 1 clinical trial of OP0201, the company's lead product candidate being developed for otitis media.

"The initiation of this phase 1 study represents a significant milestone for the company. Completion of this safety study will position us to quickly move forward and evaluate OP0201 in children with otitis media," said Dr. Catherine Turkel, President of Novus Therapeutics. "Otitis media affects millions of people around the world, particularly young children, and can become extremely burdensome to patients and their caregivers. Given the lack of any approved pharmaceutical treatment options, OP0201 has the potential to be a transformational, first-in-class treatment option that addresses the underlying cause of otitis media."

Study OP0201-C-002 ("C-002") is a phase 1 clinical trial designed to evaluate safety and tolerability of daily intranasal administration of OP0201 over 14 consecutive days in 30 healthy adults. The randomized, double-blind, placebo-controlled, parallel-group, dose-escalation trial will include a 30 mg per day (Cohort A) and 60 mg per day (Cohort B) dose of OP0201. The single center study will be conducted in the United States. Additional information about the study can be found at https://clinicaltrials.gov/ using the identifier NCT03748758.

"If ultimately approved by health authorities, OP0201 may fundamentally alter the current treatment paradigm for otitis media and provide a non-invasive alternative to surgical insertion of ventilation tubes into the tympanic membrane - commonly known as the eardrum," concluded Dr. Turkel.

About OP0201

OP0201 is being developed as a potential first-in-class treatment option for otitis media ("OM"), which is often caused by Eustachian tube dysfunction ("ETD"). OP0201 is a drug-device combination product comprised of a proprietary formulation of a surfactant (dipalmitoylphosphatidylcholine or "DPPC") and a spreading agent (cholesteryl palmitate or "CP") suspended in propellant. The product is administered intranasally via a pressurized metered-dose inhaler ("pMDI") and is intended to be used to restore the normal physiologic activity of the Eustachian tube ("ET"), which is the small tube that connects the middle ear to the back of the nasopharynx. Together DPPC and CP are designed to effectively absorb to the air-liquid interface of the mucosa and reduce the interfacial surface tension of the ET, which reduces the passive pressure required for the ET to open. In other words, OP0201 is intended to promote 'de-sticking' of the ET so that ventilation and drainage of the middle ear may occur.

About Novus Therapeutics

Novus Therapeutics, Inc. ("Novus") is a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat ("ENT"). Novus has two technologies, each that has the potential to be developed for multiple ENT indications. Novus' lead product candidate (OP0201) is a surfactant-based, drug-device combination product being developed as a potential first-in-class treatment option for patients at risk for, or with, otitis media ("OM" or middle ear inflammation with or without infection). Globally, OM affects more than 700 million adults and children every year, with over half of the cases occurring in children under five years of age. OM is one of the most common disorders seen in pediatric practice, and in the United States is a leading cause of health care visits and the most frequent reason children are prescribed antibiotics or undergo surgery. Novus also has a foam-based drug delivery technology (OP01), which may be developed in the future to deliver drugs into the ear, nasal, and sinus cavities. For more information please visit novustherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements that involves substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, and other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding: expectations regarding the timing for the commencement and completion of product development or clinical trials; the rate and degree of market acceptance and clinical utility of the company's products; the company's commercialization, marketing and manufacturing capabilities and strategy; the company's intellectual property position and strategy; the company's ability to identify additional products or product candidates with significant commercial potential; the company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; developments relating to the company's competitors and industry; and the impact of government laws and regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability to develop commercially viable product formulations; the sufficiency of the company's cash resources; the ability to obtain necessary regulatory and ethics approvals to commence additional clinical trials; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of any investigational product; whether any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if we are able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward -looking statements contained herein, are discussed in our quarterly report on Form 10-Q for the quarter ended September 30, 2018, as well as other filings with the SEC which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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